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**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

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MF

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/738,808	12/15/00	SALAMONE J	P02389

IM22/1106

ROBERT B. FURR, JR.
LAW DEPARTMENT
BAUSCH & LOMB INCORPORATED
ONE BAUSCH & LOMB PLACE
ROCHESTER NY 14604

EXAMINER

SIOUBRA, I

ART UNIT	PAPER NUMBER
1744	8

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/738,808

Applicant(s)

SALAMONE ET AL.

Examiner

Imad Soubra

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 20) ☐ Other: _____

DETAILED ACTION

Specification

1. Applicant is reminded of the proper content of an Abstract of the Disclosure. In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. The length of the abstract should be at least 50 words and no more than 250 words used to summarize the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.

Ascertaining the differences between the prior art and the claims at issue.

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- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable by Nicolson et al in view of Thiele. Nicolson et al intrinsically discloses a similar composition for the prevention of preserving uptake into biomaterials as applicant is claiming. Nicolson et al teaches that the object of the invention is to provide an ophthalmic lens capable of extended continuous wear periods of at least 24 hours without substantial corneal swelling or consumer discomfort, and more preferably, to provide a lens capable of continuous wear of 4, 7, 14 or 30 days or more without substantial conceal swelling or consumer discomfort. Yet another object of the invention is to provide methods of forming an extended-wear ophthalmic lens (column 2, lines 52-63). Nicolson et al further teaches that ionoperm polymerizable materials include a wide range of materials which may be polymerized to form a polymer displaying a relatively high ion diffusion rate therethrough; in addition, these materials must be relatively ophthalmically compatible; these ionoperm polymerizable materials include, without limitation thereto, acrylates and methacrylates, such as 2-hydroxyethyl methacrylate and so forth (column 7, lines 7-20). Nicolson et al also teaches that a wide variety of additional polymerizable materials may be include in the mixture prior to polymerization; cross-linking agents, such as ethylene glycol dimethacrylate (EGDMA), may be added to improve structural integrity and mechanical strength; antimicrobial polymerizable materials such as poly(quaternary ammonium) salts may be added to inhibit microbial growth on the lens

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material (column 7, lines 42-54). The teaching for the use of the phoshate group in preparing the solution is taught in column 12, line 64- column 13, line 8. The limitation for the addition of poly(ethylene glycol) in a mixuture is seen in column 19, line 41. Also, the contact lenses made out of silicone hydrogel in which is notoriously well known in the art under other publications where the title suggest this inherently property of contact lenses. The reference further teaches that suitable hydrophilic comonomers (a) are, without this being an exhaustive list, hydroxyl-substituted lower alkyl acrylates. and the references the teaches the variations can be used from this group (column 26, line 62-column 27, line 25).

On the other hand, the patent of Nicolson et al fails to disclose the ability of the antimicrobials not be able to adhere onto the biomaterial. However, the Thiele reference discloses the concept of inhibiting the adherence of antimicrobial on the biomaterial. Thiele teaches that algae have polysaccharide similar to those of bacteria; one theory is that cells can be made to adhere very rapidly to any surface carrying a positive charge by means of coulombic attractions; certain environmental enzymes, and enzymes from damaged or dead tissues, plus from inflammatory cells, inhibit cell adhesion either directly or indirectly (column 2, lines 56-63). Thiele further suggests that one theoretical explanation of the broad spectrum of antimicrobial applications of the liquefied compositions of this invention is in essence apparently its cationic and/or chemotactic ability to react or act upon the surface of all cells which have become polarized as a result of injuries, traumas, burns, toxins or infections (column 3 – line 67-

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column 4, line 5). Thiele also teaches that the first test of Example 4 was repeated using streptococcus pyogenes; the dilution factor was the same, but there was heavy growth on the invention treated plate, but there was heavy growth on the untreated plate; it is believed that the invention composition keeps the microorganism cells from proliferating and adhering (column 22, lines 39-46). The motivation for combining the two references would be to force the microorganism away from the biomaterial. Therefore, it would have been obvious of one having ordinary skill in the art at the time that the invention was made to incorporate the property of not having biomaterial microorganism adhering to biomaterial in order to prevent from an accumulation of organism onto the biomaterial.

3. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolson et al in view of Thiele, as applied in the claims above, and in further view of Billmers et al. Nicolson et al fails to disclose that the cationic polysaccharide consisting of cationic starch. However, the patent of Billmers et al does teach this limitation in his invention. Billmers et al teaches that the modification of starch and other polysaccharides by chemical derivatization to produce various cationic polysaccharides is well known; cationic polysaccharides, i.e., polysaccharides which have been modified so that they have a positive electrostatic charge, are used for a large number of applications and are particularly useful in the manufacture of paper due to their superior performance in the paper production as compared to unmodified polysaccharides (column 1, lines 18-31). Billmers et al further teaches that the term "paper" includes sheet-like masses and

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molded products made from fibrous cellulosic material, which may be derived from natural sources as well as from synthetics such as polyamides, polyesters and polyarylic resins, as well as from mineral fibers such as asbestos and glass (column 1, lines 32-39). The motivation for combining the two references would be to show that using starch cationic creates a stronger material. Therefore, it would have been obvious of one having ordinary skill in the art at the time the invention was made to incorporate the starch cationic of Billmers et al into the solution of Nicolson et al in order to have a better quality of material produced.

Conclusion

Any inquiry concerning this communication from the examiner should be directed to Imad Soubra whose telephone number is (703) 305-3541. The examiner can normally be reached on 8:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-5408 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1193.

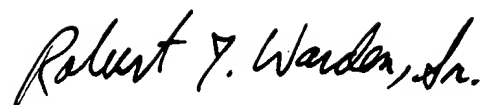
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Imad Soubra

April 16, 2001

A handwritten signature in black ink, reading "Robert J. Warden, Sr." in a cursive script.

ROBERT J. WARDEN, SR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700